UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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THERESA PITMAN, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

IMMUNOVANT, INC. f/k/a HEALTH SCIENCES ACQUISITIONS CORPORATION, RODERICK WONG, PETER SALZMANN, FRANK M. TORTI, ANDREW FROMKIN, DOUGLAS HUGHES, GEORGE MIGAUSKY, ATUL PANDE, ERIC VENKER, SVB LEERINK LLC, LIFESCI CAPITAL LLC, CHARDAN CAPITAL MARKETS LLC, GUGGENHEIM SECURITIES, LLC, ROBERT W. BAIRD & CO. INCORPORATED, and ROIVANT SCIENCES LTD.,

Defendants.
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MEMORANDUM AND ORDER
21-cv-918 (KAM)(VMS)

MATSUMOTO, United States District Judge:

On February 19, 2021, Plaintiff Theresa Pitman ("Pitman") filed a class action suit on behalf of herself and other purchasers of the securities of Defendant Immunovant, Inc. f/k/a/ Health Sciences Acquisition Corporation ("Immunovant") alleging several violations of federal securities laws by Defendant Immunovant; Immunovant's Chief Executive Officer, Peter Salzman ("Salzman"), Immunovant's Chief Financial Officer, Pamela Yanchik Connealy ("Connealy"), and Immunovant's former President and Chief Executive Officer, Roderick Wong ("Wong"). (ECF No. 1, Complaint, "Compl.")

In the operative Third Amended Complaint[1], Lead Plaintiff SEPTA Pension Plan Master Trust ("Plaintiff" or "SEPTA")[2] alleges that Defendants[3] made material misstatements and omissions regarding the development, testing, and marketing of IMVT-1401, a drug that was developed to treat autoimmune diseases (the "Drug"), including with respect to the Fall 2020 Offering Documents.[4] (ECF No. 82, Third Amended Complaint, "TAC".)

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[1] In its objections, Plaintiff refers to the operative pleading as the Second Amended Complaint and in their responses, Defendants follow suit. It is not clear to this Court why the parties would refer to the pleading as such. As noted in the R&R, Pittman filed a Complaint on February 19, 2021 (ECF No. 1); Plaintiff SEPTA Pension Plan Master Trust ("SEPTA" or "Plaintiff") filed an Amended Complaint on February 1, 2022, following Magistrate Judge Scanlon's appointment of SEPTA as lead Plaintiff (ECF No. 29); Plaintiff filed a Second Amended Complaint on March 15, 2022 (ECF No. 44); and on March 17, 2023, Plaintiff filed the operative Third Amended Complaint. (ECF No. 82.) The fact that Plaintiff refers to its pleading as the "Second Amended Complaint" does not make it a Second Amended Complaint. The Court has liberally granted Plaintiff' leave to amend the Complaint on three occasions. The operative pleading is the Third Amended Complaint. (ECF No. 82.)

[2] By the time the Third Amended Complaint was filed, Magistrate Judge Scanlon had resolved competing motions by Immunovant investors Bucks County Employees Retirement System, Erie County Employees' Retirement System, and SEPTA Pension Plan Master Trust ("SEPTA") to be appointed as lead Plaintiff and to have their respective counsel appointed as lead counsel for the class. The Court granted SEPTA's motion on December 29, 2021 and SEPTA was appointed lead Plaintiff. (ECF No. 18.)

[3] The Third Amended Complaint also included additional parties as named defendants, including the Chairperson of the Immunovant Board of Directors, Frank M. Torti ("Torti") and members of the Immunovant Board of Directors, Andrew Fromkin ("Fromkin"), Douglas Hughes ("Hughes"), George Migausky ("Migausky"), Atul Pande ("Pande"), and Eric Venker ("Venker") (together, with Connealy, Wong, and Salzman, the "Individual Defendants" and all together with Immunovant, the "Immunovant Defendants"). The Third Amended Complaint also named as additional defendants SVB Securities LLC f/k/a SVB Leerink LLC, LifeSci Capital LLC, Chardan Capital Markets LLC, Guggenheim Securities, LLC, and Robert W. Baird & Co. Inc. (together, the "Underwriter Defendants"). Finally, the Third Amended Complaint included Roivant Sciences Ltd. ("Roivant") as a defendant. On May 17, 2022, Connealy was dismissed by stipulation of dismissal. (ECF No. 46.)

[4] All capitalized terms not explicitly defined herein correspond to the definitions set forth in Magistrate Judge Scanlon's R&R.

Plaintiff further alleges that Defendants' material misstatements and omissions had the effect of inflating the share price of Immunovant securities, which conferred benefits upon Defendants at Plaintiff's expense. Plaintiff contends that Defendants' conduct constitutes violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933, 15 U.S.C. § 77a, *et seq.* ("Securities Act"), and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a, *et seq.* ("Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4, *et eq.* ("PSLRA") and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5 ("Rule 10b-5"). (TAC ¶ 1.)

On June 30, 2023, the Immunovant Defendants moved to dismiss the Third Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 87, Immunovant Defendants' Motion to Dismiss, "Immunovant Def. Mot.") The Underwriter Defendants also moved on June 30, 2023 to dismiss the Third Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6). (ECF No. 90, Underwriter Defendants' Motion to Dismiss, "Underwriter Def. Mot.") The remaining Defendant, Riovant, moved to dismiss the Third Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) on June 30, 2023 as well. (ECF No. 92, Defendant Riovant's Motion to Dismiss, "Riovant Def. Mot.") Plaintiff opposed the three motions to dismiss the Third Amended Complaint. (ECF No.

90, Plaintiff's Opposition, "Ptf. Opp.") By order dated July 5, 2023, this Court referred each of the three motions to dismiss the Third Amended Complaint filed by the Immunovant Defendants, the Underwriter Defendants, and Riovant respectively to Magistrate Judge Vera M. Scanlon for a report and recommendation pursuant to 28 U.S.C. § 636(b).

Presently before the Court is the Report and Recommendation issued on February 25, 2024 by Magistrate Judge Scanlon, recommending that this Court grant all three motions to dismiss the Third Amended Complaint in it is entirety. (ECF No. 103, "R&R" at 46.) The R&R recommends that leave to replead be denied, given the four prior opportunities for Plaintiff to state viable claims. (*Id.*) The R&R described "the overarching issue pertaining to both the Securities Act and the Exchange Act claims presented by Plaintiff's allegations" as follows:

> [W]hether Defendants' challenged statements were material misrepresentations or omissions because the clinical trials for the Drug should have been designed differently, such that cholesterol levels should have been monitored in earlier phases of the trials, and because the decision not to monitor cholesterol in earlier phases of the trials should be haven disclosed to investors, in view of, in Plaintiff's view, the clear link between the Drug and decreased albumin levels . . . and elevated cholesterol levels. The inquiry underlying both related allegations is whether, together, the pre-clinical monkey studies and the available scientific literature, the scientific literature indicating that thyroid eye disease affects cholesterol level and the fact that [other companies] monitored cholesterol levels when developing similar compounds, demonstrate the

> scientific fact that increased cholesterol levels were a key potential risk of the Drug.

(R&R at 12-13.)

The R&R found that in addition to faulting the design of Defendants' clinical trials, "Plaintiff's allegations against Defendants are founded on a fundamental disagreement as to the interpretation of scientific data," including data from the Drug's clinical trials, and other scientific literature. (R&R at 16.) In accordance with Second Circuit law, Magistrate Judge Scanlon concluded that competing interpretations or analyses of scientific data are not actionable under federal securities law and, therefore, that Plaintiff had failed to allege adequate facts to support a claim that Defendants' statements constitute material misrepresentations or omissions and failed to plead scienter with respect to the Exchange Act claims. (R&R at 16.) The R&R recommends that each of the Securities Act and Exchange Act claims be dismissed on this basis.

The R&R also recommends that the Exchange Act claims be dismissed because Plaintiff failed to allege adequate facts showing scienter. Because the R&R recommends dismissal of the primary violations alleged in connection with Section 11 and Section 12(a)(2) of the Securities Act, the R&R also recommends that any allegation of control person liability under Section 15 of the Securities Act be dismissed. Similarly, because the R&R recommends dismissal of the primary violations alleged in

connection with Section 10 of the Exchange Act also and Rule 10b-5, the R&R also recommends that any allegation of control person liability under Section 20(a) of the Exchange Act be dismissed. Finally, the R&R recommended that "Plaintiff be denied leave to replead" because "the significant pleading deficiencies . . . are inextricably intertwined with Plaintiff's theory of the case and are therefore not curable." (R&R at 46.) The R&R also noted that Plaintiff was granted three opportunities to amend the pleadings and persistently failed to cure the defects of the original Complaint. (R&R at 46.)

Objections to the R&R were timely filed by Plaintiff on March 11, 2024 (ECF No. 105, Plaintiff's Objections, "Ptf. Obj.") and Defendants jointly responded to Plaintiff's Objections on March 25, 2024. (ECF No. 100, "Ptf. Resp.") No other party has filed any objections to Magistrate Judge Scanlon's R&R. For the reasons stated below, upon *de novo* review and clear error review, the Court respectfully overrules Plaintiff's objections, and adopts and affirms Magistrate Judge Scanlon's meticulous and well-reasoned R&R in its entirety.

BACKGROUND

The Court assumes the parties' familiarity with the extensive facts thoroughly recounted in the R&R (R&R at 3-11), and in Magistrate Judge Scanlon's May 5, 2023 Memorandum and

Order. *See generally* (ECF No. 80.) The Court has reviewed the facts *de novo* and adopts the detailed facts from the R&R and the May 5, 2023 Memorandum and Order herein.

LEGAL STANDARD

In considering the recommendations of a Magistrate Judge, as outlined in an R&R, the Court may "accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions." Fed. R. Civ. P. 72(b)(3); *see also* 28 U.S.C. § 636(b)(1). When a party makes a timely objection to an R&R, the Court must review *de novo* those recommendations in the R&R to which the party objects. *See* Fed. R. Civ. P. 72(b)(3); *United States v. Male Juvenile*, 121 F.3d 34, 38 (2d Cir. 1997). However, even on *de novo* review, "a district [court] judge will [] ordinarily refuse to consider arguments, case law and/or evidentiary material which could have been, but [were] not, presented to the magistrate judge in the first instance." *Kennedy v. Adamo*, No. 02-cv-1776 (ENV), 2006 WL 3704784, at *1 (E.D.N.Y. Sep. 1, 2006), *aff'd* 323 F. App'x 34 (2d Cir. 2009) (quoting *Haynes v. Quality Markets*, No. 02-cv-250 (KES), 2003 WL 23610575, at *3 (E.D.N.Y. Sep. 22, 2003).

As to the portions of the R&R to which no party objects, the Court "need only satisfy itself that there is no clear error

on the face of the record." *Galvez v. Aspen Corp.*, 967 F. Supp. 2d 615, 617 (E.D.N.Y. 2013) (internal quotation marks and citations omitted). If "the [objecting] party makes only frivolous, conclusory or general objections, or simply reiterates [] original arguments, the Court reviews the [R&R] only for clear error." *Velez v. DNF Assocs., LLC*, No. 19-CV-11138 (GHW), 2020 WL 6946513, at *2 (S.D.N.Y. Nov. 25, 2020) (internal citations omitted). Furthermore, "where the objections are merely perfunctory responses, argued in an attempt to engage the district court in a rehashing of the same arguments set forth in the original petition, [district] courts should review [the R&R] for clear error" only. *Chen v. New Trend Apparel, Inc.*, 8 F. Supp. 3d 406, 416 (S.D.N.Y. 2014) (quoting *Silva v. Peninsular Hotel*, 509 F. Supp. 2d 364, 366 (S.D.N.Y. 2007)).

DISCUSSION

The Court finds that Plaintiff's objections, "*in toto*, are of a conclusory, and general nature thus triggering only clear error review." *Kamden-Ouaffo v. Balchem Corp.*, No. 17-cv-2180 (PMH), 2021 WL 1101126, at *2 (S.D.N.Y. Mar. 23, 2021). Plaintiff's objections either largely restate Plaintiff's previously articulated arguments or make broad, perfunctory allegations that the R&R is wrong. Indeed, several of

Plaintiff's objections are no more than conclusory statements that the recommendations in the R&R are wrong because Plaintiff's allegations are right. *See e.g.*, (Ptf. Obj. at 19) (Plaintiff "objects to the [] finding in the R&R that the statements in the [Fall] 2020 Offering Documents were not misleading because the [TAC] alleges facts . . . that those statement were misleading.") Objections of this nature trigger the Court's review of the R&R for clear error. *See Barratt v. Joie*, No. 96-CV-0324(LTS), 2002 WL 335014, at *1 (S.D.N.Y. Mar. 4, 2002) ("[O]bjections stating the magistrate judge's decisions are wrong and unjust, and restating relief sought and facts upon which complaint grounded, are conclusory"); *Amaya v. Ballyshear LLC*, No. 17-cv-1596(JS), 2023 WL 2596031, at *3 (E.D.N.Y. Mar. 22, 2023) ("[W]here a party 'makes only conclusory or general objections, or simply reiterates the original arguments, the Court reviews the [R&R] only for clear error.'") (internal citation omitted). Nevertheless, the Court applies both clear error and *de novo* review to Plaintiff's objections, and respectfully overrules each objection in turn below.

I. Factual Inferences

Plaintiff first objects to the R&R insofar as it "fails to draw inferences in Plaintiff's favor, inappropriately draws inferences in favor of Defendants, and inappropriately considers

facts not alleged in the [TAC] or properly in the record."[5] (Ptf. Obj. at 11, 22.) The Court considers this objection *de novo* and overrules the objection.

A. The Summary of Overarching Issues

Plaintiff first alleges that the R&R "incorrectly describes as an 'overarching issue' for both Plaintiff's Securities Act and Exchange Act claims whether Defendants' statements were material misrepresentations or omissions because the clinical trials should have been designed differently." (Ptf. Obj. at 12.) Plaintiff contends that the Third Amended Complaint "does not allege how Immunovant should have designed its clinical trials." (Ptf. Obj. at 12.) Plaintiff's argument that the Third Amended Complaint does not challenge the design of Immunovant's clinical trials was also raised before Magistrate Judge Scanlon in opposition to the motions to dismiss. *See* (Ptf. Opp. at 64) ("This action does not relate to a disagreement about [the] clinical trial design.") Because Plaintiff "simply reiterates [its] original

[5] Plaintiff raises these same objections several times. First, Plaintiff argues that the R&R "fails to draw inferences in Plaintiff's favor, inappropriately draws inferences in favor of Defendants, and inappropriately considers facts not alleged in the [TAC] or properly in the record" in connection with the R&R's finding that Plaintiff fails to adequately allege claims under the Securities Act. (Ptf. Obj. at 11.) Plaintiff again raises this same objection–that the R&R "fails to draw inferences in Plaintiff's favor, inappropriately considers facts not properly before the Court, and inappropriately draws inferences in Defendants' favor" and specifically references the identical objections "discussed [] in connection with Plaintiff's Securities Act claims." (Ptf. Obj. at 21.) Because these objections relate to the same core nucleus of facts that are applicable to both the Securities Act claims and Exchange Act claims, the Court addresses the substance of the objections together.

arguments," the Court need not review this objection *de novo*. *Pall Corp. v. Entegris, Inc.*, 249 F.R.D. 48, 51 (E.D.N.Y. 2008). In any event, upon *de novo* review, the Court overrules this objection.

Plaintiff's assertion that the Third Amended Complaint "does not allege how Immunovant should have designed its clinical trials" (Ptf. Obj. at 12), is difficult to reconcile with Plaintiff's own prior allegations in the Third Amended Complaint, including that "Immunovant should have designed each of the phase 1 and 2 clinical trials so that each of the participants' cholesterol was tested and monitored." (TAC ¶¶ 119, 304); *see also* (TAC ¶ 91(d) ("elevated cholesterol levels . . . needed to be monitored and assessed"); (TAC ¶ 98) (The Drug's "clinical studies should have monitored and assessed this risk"). The Court rejects Plaintiff's mistaken assertion that its pleadings did not allege that "Defendants . . . should have designed its clinical trials differently" because that characterization is "contradicted by other matters asserted or relied upon . . . by [] [P]laintiff in [] the [Third Amended Complaint]." *Tsinberg v. City of New York*, 20-cv-719 (PAE), 2021 WL 1146942, at *4 (S.D.N.Y. Mar. 25, 2021).

Contradicting the allegations in the Third Amended Complaint, Plaintiff now argues that "Immunovant was free to design its trials as it wanted" and contends that the real focus of

the Third Amended Complaint is Defendants' failure to "provide complete and accurate disclosures" to investors about the decision not to monitor patients' cholesterol levels in early trials. *See* (Ptf. Obj. at 13) ("Had Defendants simply advised investors that they did not monitor cholesterol in the early clinical trials . . . Plaintiff would not have alleged Defendants' statements were misleading." (Ptf. Obj. At 13.) Magistrate Judge Scanlon aptly addresses Plaintiff's allegations regarding the disclosure of the Drug's clinical trial design as follows:

> The Court views the overarching issue pertaining to both the Securities Act and the Exchange Act claims presented by Plaintiff's allegations and, by extension, Defendants' motions to dismiss, to be whether Defendants' challenged statements were material misrepresentations or omissions *because the clinical trials for the Drug should have been designed differently*, such that cholesterol *levels should have been monitored in earlier phases of the trials*, and **because the decision not to monitor cholesterol in earlier phases of the trials should have been disclosed to investors**, in view of, in Plaintiff's view, the clear link between the Drug and decreased albumin levels, as well as between decreased albumin levels and elevated cholesterol levels.

(R&R at 12-13)(emphasis added).

On *de novo* review, the Court finds that Plaintiff's objection that the R&R mischaracterizes the focus of its claims contradicts Plaintiff's own statements in Third Amended Complaint. To the extent such contradictions comprise an effort to amend the Third Amended Complaint, the Court declines to permit further amendment of the Third Amended Complaint, as described further below. *See also Kleinman v. Elan Corp., PLC*,

706 F.3d 145, 153 (2d Cir. 2013) ("[A] party may not amend pleadings through a brief.") Plaintiff's attempt to distinguish between Plaintiff's opposition to the design of the clinical trials, and Plaintiff's opposition to the statements Defendants made about the clinical trial *because of* Plaintiff's opposition to the trial design, is not supported by the law. *Compare* (Ptf. Obj. at 58) (Defendants "statements were materially false because Immunovant should have – but failed to – perform ongoing surveillance of . . . elevated LDL and total cholesterol levels"), *with In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13-cv-755 (KBK), 2014 WL 585658, at *10 (S.D.N.Y. Feb. 14, 2014) ("[P]laintiffs assert that, given the extent of the methodological flaws, defendants' statements regarding the [] results were actionable misstatements or half-truths. Plaintiffs are incorrect; these allegations fail as a matter of law."). Either way, even on *de novo* review, Plaintiff's objection to Magistrate Judge Scanlon's description of the "overarching issue" of Plaintiff's claims (R&R at 12), is frivolous and is overruled. *See Velez*, 2020 WL 6946513, at *2 (If "'the [objecting] party makes only frivolous, conclusory or general objections . . . the Court [should] review[] the report and recommendation only for clear error.'")(internal citation omitted).

B. Interpretation of Scientific Data

Plaintiff next objects to the R&R insofar as it "incorrectly frames each of Plaintiff's claims as being about a dispute over the proper interpretation or analysis of scientific data." (Ptf. Obj. at 13) (citing R&R at 13.)[6] By contrast, Plaintiff insists that the Third Amended Complaint "alleges that Defendant failed to disclose an important potential risk of [the Drug]" and that "Defendants' descriptions of the drug as safe and well-tolerated were misleading." (Ptf. Obj. at 13.) Plaintiff alleges that these allegations constitute material misstatements and omissions and are not simply opinion statements, disagreements, or disputes about the proper interpretation of scientific data.

Here too, this objection does not warrant *de novo* review because it "recites the same argument[] presented to the magistrate judge." *Emerson Electric Co. v. Holmes*, 16-cv-1390 (PKC), 2020 WL 4592808, at *6 (E.D.N.Y. Aug. 11, 2020) (internal citation omitted) ("[O]bjections that are merely perfunctory responses argued in an attempt to engage the district court in a

[6] Plaintiff makes this objection, both generally and as it relates to specific allegations in the Third Amended Complaint, throughout its brief. *See* (Ptf. Obj. at 17) ("[T]he R&R states that 'Plaintiff's allegations against Defendants are founded on a fundamental disagreement as to the interpretation of scientific data' . . . Plaintiff objects to the R&R because it fails to credit Plaintiff's well pled allegations."); (Ptf. Obj. at 24) ("The R&R . . . states that a disagreement as to the interpretation of scientific data is not a basis" for relief, but "not every statement Plaintiff challenges as misleading can be classified as a disagreement."); The Court addresses all of Plaintiff's objections that are based on the notion that the R&R incorrectly regards Plaintiff's alleged misstatements and omissions as inactionable disagreements about the interpretation of scientific data all together.

rehashing of the same arguments set forth in the original papers will not suffice to invoke *de novo* review.") Indeed, Plaintiff presented this exact argument to Magistrate Judge Scanlon in opposition to the motions to dismiss. *See e.g.*, (Ptf. Opp. at 24) ("Defendants . . . erroneously [argue that] Plaintiff's claims relate to scientific disagreements over the interpretation of data and clinical results."); (ECF No. 95 at 58) ("Plaintiff is not disputing the interpretation or analysis of clinical trial data."); (Ptf. Opp. at 66) ("Plaintiff is not disputing the interpretation of the reported results from [the Drug's] clinical trials."); (Ptf. Opp. at 70) ("Plaintiff does not dispute how Immunovant interpreted or described data.").

Nevertheless, even on *de novo* review, Magistrate Judge Scanlon's finding in the R&R that "Plaintiff's allegations against Defendants are founded on a fundamental disagreement as to the interpretation of scientific data" is an accurate description of Plaintiff's own allegations in the Third Amended Complaint. (R&R at 16.) Plaintiff first cites its allegation "that elevated cholesterol was an important risk of [the Drug]," and argues that the R&R "incorrectly minimizes . . . studies show[ing] 200 to 300 percent increases in cholesterol." (Ptf. Obj. at 17.) Plaintiff's statement that the "studies show[ing] 200 to 300 percent increase in cholesterol" constitute evidence of the importance of the risks posed by the Drug is, of course,

an interpretation of those studies. The R&R considered Plaintiff's allegations regarding the weight and importance of "a) the pre-clinical monkey studies and the available scientific literature about the monkey studies, b) scientific literature . . . [regarding] thyroid eye disease . . . and c) [the fact] that [other companies] monitored cholesterol levels when developing similar compounds" and found that Plaintiff's allegations about the meaning of this data amounts to an interpretation of the data. (R&R at 16.) In referring to Plaintiff's allegations as an interpretation of the scientific data, the R&R does not take a position on the veracity or strength of the underlying data. Nor does Magistrate Judge Scanlon's acknowledgement in the R&R that Defendants may reasonably disagree with Plaintiff's interpretation of that data minimize the data itself. This Court agrees that "[a]t bottom, [Plaintiff's] allegations regarding Defendants' [statements] about the" clinical trial design and scientific data "are little more than a dispute about the proper interpretation of data." *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016). Accordingly, Plaintiff's objection is overruled.

C. Interpretation of the Animal Studies Reports

Plaintiff next objects to the R&R insofar as the R&R allegedly "gives undue weight to the indications in the summary portion of the [animal studies] report that there were only

minor increases in cholesterol." (Ptf. Obj. at 17.) As before, Plaintiff "simply reiterates [its] original arguments," such that the Court need not review this objection *de novo*. *Pall Corp. v. Entegris, Inc.*, 249 F.R.D. 48, 51 (E.D.N.Y. 2008). *See* (Ptf. Opp. at 36) ("the summary portion [of the report] was wrong and false [], and not the result of a scientific disagreement or difference of opinion.")

Even on *de novo* review, however, the Court overrules Plaintiff's objection. Plaintiff argues that Magistrate Judge Scanlon "should have accepted as true Plaintiff's allegation that the summary of the data was wrong for pleading purposes." (Ptf. Obj. at 20.) To the contrary, Magistrate Judge Scanlon was under no such obligation to accept Plaintiff's interpretation of the data. Instead, the R&R identified competing interpretations of data, which are not actionable. *See Fisk v. Letterman*, 401 F. Supp. 2d 362, 368 (S.D.N.Y. 2005) (The Court "is not obliged to reconcile plaintiff's own pleadings that are contradicted by other matters asserted or relied upon or incorporated by reference by a plaintiff in [] the complaint.") In any event, the R&R does not "give undue weight" (Ptf. Obj. at 17), or any weight at all, to the summary portion of the report. Rather, the R&R merely notes that there is a "discrepancy" between the Former Employee's conclusion as to the data that the animals experienced significant increases

in cholesterol levels . . . [and] the summary of the data . . . [which] concludes that cholesterol level increases were only mild." (R&R at 42) (Explaining that "the discrepancy . . . indicate[s] [a] disagreement as to the interpretation of the data.") (R&R at 42.) The Third Amended Complaint describes the discrepancy, but Plaintiff now takes issue with the R&R's "descri[ption] [of] the discrepancy . . . as a disagreement." This is a distinction without meaning. Magistrate Judge Scanlon accurately describes the discrepancy as a disagreement in reliance on Plaintiff's own factual allegations in the Third Amended Complaint. Accordingly, Plaintiff's objection is overruled.

D. Reasonable Investor

Plaintiff also objects to the R&R's "conclu[sion] that the omitted facts from the [Fall] 2020 Offering Documents would not substantially undermine the conclusion of a reasonable investor." (Ptf. Obj. at 19.)[7] Plaintiff contends that "it cannot be seriously disputed that the eventual reported elevations in cholesterol were material facts, as shown by the

[7] Plaintiff also argues that "for the same reasons Plaintiff objects to the R&R's recommendations regarding the misrepresentations and omissions in the [Fall] 2020 Offering Documents, Plaintiff objects to the R&R with respect to its rejection of Plaintiff's Item 303 and 105 claims." (Ptf. Obj. at 21.) The Court respectfully overrules Plaintiff's objections to the R&R's findings and recommendations regarding the Fall 2020 Offering Documents and, accordingly, overrules Plaintiff's objections to the R&R's findings regarding the Item 303 and 105 claims because Plaintiff's objections to those claims are based on the same arguments made in connection with the Fall 2020 Offering Documents, which the Court has overruled. (*Id.*)

halting of the [] study . . . [such that] [a]n inference should therefore be drawn in favor of Plaintiff that the failure to disclose [the] elevations in cholesterol were an important potential risk was also material." (Ptf. Obj. at 19-20.) This is exactly the sort of argument that courts within the Second Circuit routinely reject as impermissible hindsight. *See Rubinstein v. Credit Suisse Group AG*, 457 F. Supp. 3d 289, 295 (S.D.N.Y. 2020) ("A plaintiff may not plead a Section 11 claim 'with the benefit of 20/20 hindsight' or base the claim on a 'backward-looking assessment' of the registration statement.") Moreover, Plaintiff's objection "to the [] finding in the R&R that the statements in the [Fall] 2020 Offering Documents were not misleading" on the basis that "the [TAC] alleges facts raising a plausible inference that those statement were misleading" (Ptf. Obj. at 19), amounts to an argument that the R&R is incorrect because Plaintiff is correct. As previously noted, objections that merely argue a magistrate judge's decision is "wrong" are conclusory and do not warrant *de novo* review. *Barratt*, 2002 WL 335014, at *1. Even on *de novo* review however, Plaintiff's objection is overruled because Plaintiff cannot impermissibly rely on hindsight regarding the eventual halting of the clinical trials to support its claims.

E. Reasonableness of Defendants' Interpretations

In the alternative, Plaintiff states that "even if some of [its] claims are properly considered a scientific dispute, as opposed to simply factual or opinion statements, the R&R incorrectly determines that Defendants' interpretations were reasonable" and in doing so, draws factual inferences in favor of Defendants. (Ptf. Obj. at 14.) Putting aside the flawed premise that "opinion statements" can form the basis for any of Plaintiff's claims, Plaintiff provides no legal authority for the assertion that the finding that Defendants' interpretations are "reasonable" constitutes an impermissible inference in Defendants' favor. To the contrary, the Second Circuit held, in the very case cited by Plaintiff, *Kleinman v. Elan Corp., plc*, 706 F.3d 145 (2d Cir. 2013), that "where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement" and affirmed a district court's dismissal of the plaintiff's amended complaint as a result. *Kleinman*, 706 F.3d at 154. In describing this objection, Plaintiff cites page 13 of the R&R, which simply sets forth the legal standard for the Court's consideration of "competing analys[es] or interpretation[s] of data" in the securities fraud context on a motion to dismiss. (Ptf. Obj. at 13.) To the extent Plaintiff objects to any of the statements in this section of the R&R, all of which appear to be descriptions of or quotes from Second

Circuit cases, Plaintiff's objection must be overruled as contrary to Second Circuit law.

In any event, Magistrate Judge Scanlon did not credit Defendants' interpretations and analyses as true. Nor does the R&R find that Plaintiff's interpretations and analyses are false. The R&R applies the governing standard for assessing competing interpretations of scientific data and correctly finds that "reasonable scientific disagreement between Plaintiff and Defendants is not the permissible subject of a securities fraud action." (R&R at 17.) Accordingly, Plaintiff's objections are overruled.

F. Compliance with Good Clinical Practices (GCP)

Plaintiff next alleges that "there are no facts in the record from which one can draw the conclusion that the FDA reviewed whether the early clinical trials were conducted in accordance with GCP." (Ptf. Obj. at 16.) Plaintiff alleges in the Third Amended Complaint that Defendants stated in the September 2020 Offering Documents that "the FDA drug approval process requires the 'performance of adequate and well-controlled human clinical trials in accordance with . . . GCP. And other . . . regulations and guidance." (TAC ¶ 151.) Plaintiff contends that this statement "created the untrue perception that Immunovant's clinical trials complied with [GCP]," but that "[c]ontrary to those statements, [the] clinical

trials failed to comply with [GCP] because they had not monitored or assessed the key potential risk of elevated LDL or cholesterol levels." (TAC ¶ 151.)

Notably, the R&R does not conclude that Defendants complied with GCP. To the contrary, the R&R simply finds that Defendants statements suggesting that it complies with GCP is, under Second Circuit law, a statement of opinion and is not actionable. *See Philip Morris*, 89 F.4th at 419 ("Defendants' statements regarding GCP compliance are necessarily statements of opinion.")

Finally, Plaintiff's statement that "the R&R should have viewed all of Plaintiff's allegations together, instead of in isolation" (Ptf. Obj. at 18), is undermined by the fact that the R&R did, in fact, view Plaintiff's allegations all together, in addition to examining each alleged misstatement or omission individually. *See* (R&R at 12-13) ("The inquiry . . . is whether, together, the pre-clinical monkey studies and the available scientific literature, the scientific literature indicating that thyroid eye disease affects cholesterol levels and the fact that Harbour and Argenx SE monitored cholesterol levels when developing similar compounds, demonstrate the scientific fact that increased cholesterol levels were a key potential risk of the Drug.") Accordingly, this objection is respectfully overruled.

II. Relevant Case Law

Plaintiff objects to the R&R's reference to the Second Circuit's recent decision in *Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408 (2d Cir. 2023). Plaintiff argues that because the Second Circuit's decision in *Philip Morris* was issued "on December 26, 2023, months after Defendants' motions to dismiss had been fully briefed. . . . the Court should review its application *de novo*." (Ptf. Obj. at 14.) Plaintiff further argues that the factual circumstances underlying *Philip Morris*, and, therefore, the legal reasoning extrapolated form those factual circumstances, are distinguishable from and inapplicable to the facts in the instant action.[8] The Court reviews Plaintiff's objections that relate to alleged distinctions between the instant case and the circumstances underlying *Philip Morris de novo*. Upon *de novo* review, however, the Court agrees with the R&R's interpretation of the reasoning and applicability of the Second Circuit's decision in *Philip Morris* and, thus, respectfully overrules Plaintiff's objections.

[8] Plaintiff raises this objection twice. First, Plaintiff raises this objection in connection with its discussion of the Securities Act claims. (Ptf. Obj. at 14) ("The R&R relies on *Philip Morris* to reach the conclusion that it was reasonable for Defendants to not view elevated cholesterol as a potential risk.") Later, in connection with the R&R's findings regarding the Exchange At claims, Plaintiff states "for the reasons discussed above [in connection with the Securities Act claims], Plaintiff's claims are distinguishable from *Philip Morris*." (Ptf. Obj. at 22.) The Court reviews each of the objections related to the alleged distinctions between the instant case and *Philip Morris* together.

Plaintiff notes that *Philip Morris* involved challenged statements about "scientific data that [were] ultimately endorsed by the Food and Drug Administration . . . such [that the challenged] statements [were proven] per se reasonable." *Philip Morris*, 89 F.4th at 414. Plaintiff argues that "[u]nlike in *Philip Morris*, the FDA did not review or analyze [the Drug] in the context of Defendants' statement about [its] safety . . . and nothing that Plaintiff alleges to be misleading or omitted was endorsed by the FDA." (Ptf. Obj. at 15.) Accordingly, "Plaintiff objects to the R&R's determination that the reasonableness of Defendants' position is supported by the FDA review of the design of the . . . clinical trial" at Phase 1. (Ptf. Obj. at 16.)

As noted by Defendants in response to Plaintiff's Objections, the Second Circuit explicitly stated in *Philip Morris* that "defendants' statements about the implications of their data cannot be misleading merely because a regulatory body disagreed with defendants' conclusion." *Philip Morris*, 89 F.4th at 421; *see also* (Def. Resp. at 14.) Although the rule set forth in *Philip Morris* that "interpretation of [] data" which "the FDA eventually accepts" is "per se reasonable as a matter of law," the R&R does state that Defendants' interpretation of the scientific data was per se reasonable as a result of FDA acceptance of Defendants' interpretations or analysis. *Philip*

Morris, 89 F.4th at 421. The R&R merely notes that "[i]f the issues with cholesterol levels tied to the Drug were as obvious and critical as Plaintiff claims, the FDA would not have permitted the clinical trials to proceed without cholesterol monitoring." (R&R at 17.) Moreover, the R&R does not rely on the FDA approval of the design of the clinical trial to make any findings or conclusions about the veracity of Defendants' "statements which Plaintiff challenged." (Ptf. Obj. at 16.) Rather, FDA approval of the clinical trial design supports the reasonableness of the Defendants decision to design the clinical trials without cholesterol monitoring. (R&R at 16-17.)[9] Plaintiff's objection to the R&R citing and analyzing the *Philip Morris* decision is overruled.

III. Pleading Standard for the Securities Act Claims

Plaintiff states that "the R&R ignores that the [TAC] separates the Securities Act and Exchange Act claims," and "incorrectly applied Rule 9(b) instead of Rule 8 as the pleading standard for [Plaintiff's] Securities Act claims." (Ptf. Obj. at 18.) Plaintiff argues that, in fact, "Rule 8 should apply" to the Securities Act claims. In support of this argument,

[9] Plaintiff again notes here that "Plaintiff does not allege that Immunovant was required to monitor cholesterol in early clinical trials or that there were flaws in the design of the early clinical trials." (Ptf. Obj. at 16.) As set forth previously, the notion that Plaintiff does not take issue with the design of the clinical trial directly contradicts Plaintiff's own statements in the Third Amended Complaint about how the clinical trials "should have been" designed. (TAC ¶¶ 119, 304.)

Plaintiff points to the fact that the heightened pleading standard of Rule 9(b) applies to claims premised on allegations of fraud. Because "a plaintiff need allege no more than negligence to [state] a claim," pursuant to the Securities Act, Plaintiff argues that "Rule 8 should apply" to their Securities Act claims.

First, this objection does not warrant *de novo* review because it "recites the same argument[] presented to the magistrate judge." *Emerson Electric Co. v. Holmes*, 16-cv-1390 (PKC), 2020 WL 4592808, at *6 (E.D.N.Y. Aug. 11, 2020) (internal citation omitted) ("[O]bjections that are merely perfunctory responses argued in an attempt to engage the district court in a rehashing of the same arguments set forth in the original papers will not suffice to invoke *de novo* review.") Indeed, Plaintiff presented this exact argument to Magistrate Judge Scanlon in opposition to the motions to dismiss. *See* (Ptf. Opp. at 98-99) (Plaintiff argues that "[t]he Securities Act Claims, which sound in strict liability and negligence, are only subject to the notice pleading standard of Rule 8.")

Second, Plaintiff's objection is based on the statement in the R&R that Plaintiff's analysis "fails to meet this Circuit's heightened fraud standard in the Securities Act context." (R&R at 21.) However, it is clear from the face of the R&R that Magistrate Judge Scanlon found that the Third Amended Complaint

failed to state a claim for Securities Act violations under both Rule 8 and Rule 9(b).

Nevertheless, the Court reviews Plaintiff's objection *de novo* and respectfully overrules it. The very case Plaintiff cites, *Saskatchewan Healthcare Employees Pension Plan v. KE Holdings Inc.*, No. 21-cv-11196 (GHW), 2024 WL 775195 (S.D.N.Y. Feb. 26, 2024), rejects any attempt to draw a bright line rule regarding the applicable pleading standard for Securities Act claims. The Second Circuit has repeatedly ruled that "the heightened pleading standard applies to claims brought under the Securities Act if they sound in fraud." *Saskatchewan*, 2024 WL 775195, at *31; *In re Synchrony Financial Securities Litigation*, 988 F.3d 157, 173 (2d Cir. 2021) ("[W]here allegations underlying Securities Act claims are premised on fraud, the heightened pleading standard of [] Rule 9(b) applies."). Specifically, "[t]he heightened pleading standard of Rule 9(b) applies to Section 11 and Section 12(a)(2) claims insofar as the claims are premised on allegations of fraud." *Saskatchewan*, 2024 WL 775195, at *31. To determine whether a Securities Act claim is premised on allegations of fraud, courts consider whether "(1) the complaint contains merely a blanket disclaimer that the plaintiffs do not allege fraud for the purposes of the Securities Act claims; (2) the allegations themselves include classic fraud language; (3) the complaint does not show any

basis for the claims that is non-fraudulent; and (4) the plaintiffs do not separate the factual allegations supporting the fraud claims and negligence claims, but rather require the courts to parse the complaints." *Rombach v. Chang*, 355 F.3d 164, 171-172 (2d Cir. 2004). Here, the Third Amended Complaint "in substance [] charge[s] fraud." *In re Fuwei Films Sec. Litig.*, 634 F. Supp. 2d 419, 436 (S.D.N.Y. 2009).

The Third Amended Complaint contains a blanket statement that "Plaintiff does not claim for purposes of [the Securities Act claims] that Defendants . . . acted with scienter or fraudulent intent." (TAC ¶¶ 196, 204, 213.) Plaintiff's assertion that the Securities Act claims do not sound in fraud, in the face of "wording and imputations . . . that are classically associated with fraud," reflects "little, if any, effort to differentiate [the] asserted negligence claims from the fraud claims." *Rombach*, 355 F.3d at 172; *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 633 (S.D.N.Y. 2007) ("[T]he language at the beginning of each Securities Act claim disclaiming any intent to allege fraud is by itself insufficient to protect those claims from Rule 9(b)'s stringent requirements.") The Court need not credit Plaintiff's efforts to apply a negligence label to its Securities Act claims when "the gravamen of the complaint is plainly fraud." *Rombach*, 355

F.3d at 172 (citing *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1045 n.2 (9th Cir. 1996)).

Plaintiff also separates the claims under the Exchange Act from those under the Securities Act into different sections in the Third Amended Complaint. "But these formalisms do not require the Court to apply Rule 8's more liberal standard." *City of Omaha Police and Fire Retirement System v. Evoqua Water Technologies Corp.*, 450 F. Supp 3d 379, 402 (S.D.N.Y. 2020). The factual allegations in the first 73 pages of the Third Amended Complaint, including the "Substantive Allegations" section, operate as the same nucleus of operative facts for both the Securities Act and Exchange Act claims. Plaintiff incorporates "each and every allegation" from the "Substantive Allegations" section of the Third Amended Complaint, into Count I, which alleges violations of Section 11 of the Securities Act; Count II, which alleges violations of Section 12(a)(2) of the Securities Act; and Count III, which alleges violations of Section 15 of the Securities Act. *See* (TAC ¶¶ 195, 203, 212.) ("Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.")

In the "Substantive Allegations" section of the Third Amended Complaint, Plaintiff alleges that "Immunovant monitored and assessed the cholesterol levels of the animals" in early clinical trials, that the assessments "clearly showed substantial elevations

in cholesterol" such that "[t]he clear and unambiguous results from the [] animal studies established that the elevated cholesterol levels were a potential risk" for humans as well, that the Immunovant Defendants "should have monitored and assessed this risk" in later clinical trials involving humans in light of "the substantial risk" revealed by the assessments, and that, instead, the Immunovant Defendants "never disclosed that elevated cholesterol was a potential risk" or that the "Phase 2b trial was different from other clinical trials." (TAC ¶¶ 92-100.) Plaintiff further alleges that Defendants minimized potential risks in representations to investors. *See e.g.*, (TAC ¶ 114) (the Immunovant Defendants "minimized any adverse events from the phase 1 study") (TAC ¶ 146) (the Immunovant Defendants' statements "minimized the negative implications of the albumin reductions"), (TAC ¶ 147) (the Immunovant Defendants "minimized the impact of albumin reductions"), (TAC ¶ 148) (Defendants "minimized the potential negative consequences of albumin reductions."). Importantly, Plaintiff alleges that "[t]he increase in cholesterol levels in animals [and] the fact that it was an anticipated risk that [the Drug] would increase cholesterol levels in patients . . . were known events" (TAC ¶153), but that ultimately, these "undisclosed safety issues . . . threatened to delay and/or disrupt [the Drug's] prospects for commercial viability and profitability." (TAC ¶ 157.)

These same allegations are presented as the factual predicate for Plaintiff's scienter allegation in connection with its Exchange Act claims. *See e.g.*, (TAC ¶ 217) (Defendants "knew, or recklessly disregarded, that elevated LDL and cholesterol levels were potential risks of [the Drug]."); (TAC ¶ 219) (It was "known to Defendants or recklessly disregarded . . . [that] [t]here was a potential risk and anticipated risk [the Drug] would substantially increase LDL and total cholesterol levels because, among other reasons: [] Immunovant's animal studies for [the Drug] revealed a substantial increase in cholesterol for animals"). "Though plaintiff[] separate[s] [its] claims under the Securities Act and the Exchange Act and disclaim[s] fraud as a basis for [its] Securities Act claims, the[] claims rest on the same theory – that defendants knew" of information they were purportedly required to disclose. *In re HEXO Corp. Sec. Litig.*, 524 F. Supp. 3d 283, 299 n.17 (S.D.N.Y. Mar. 8, 2021). Accordingly, the Third Amended Complaint's repeated and incorporated factual "allegations underlying the Section 11 claim[s] are 'substantially intertwined' with the Exchange Act claims" and Rule 9(b) applies. *In re Meta Inc. Securities Litigation*, No. 21-cv-7203 (CBA), 2023 WL 6385563, at *10 (E.D.N.Y. Sep. 29, 2023).

Finally, even assuming, *arguendo*, that the Rule 8 pleading standard applies, Magistrate Judge Scanlon found that Plaintiff failed to state a claim under Section 11, 12(a)(2) and Section 15 because Plaintiff's "allegations against Defendants are

founded on a fundamental disagreement as to the interpretation of scientific data," which is not actionable under the Securities Act. (R&R at 16.) Accordingly, Magistrate Judge Scanlon found that Plaintiff failed to "allege[] sufficient facts to support the conclusion that Defendants misleadingly interpreted the available scientific material-namely the animal studies, literature in the field, diseases to be treated and other companies' trial designs." (R&R at 16.) Plaintiff's failure to "allege[] misrepresentations or omissions for securities law purposes" (R&R at 16) cannot be saved by the application of Rule 8. Under either pleading standard, Plaintiff must allege sufficient facts to support an inference that Defendants made material misstatements and/or omissions. Upon *de novo* review of Magistrate Judge Scanlon's R&R, this Court agrees that Plaintiff's Third Amended Complaint fails to state a claim and must be dismissed. Accordingly, Plaintiff's objection that Magistrate Judge Scanlon applied the wrong pleading standard to Plaintiff's Securities Act claim is respectfully overruled.

IV. Scienter for the Exchange Act Claims

Plaintiff argues that "[t]he R&R's scienter recommendations should be rejected because the R&R fails to recognize the strength of the underlying facts and because it does not consider the [TAC's] scienter allegations holistically." (Ptf. Obj. at 23.) This objection is conclusory and amounts to an

overbroad statement that Magistrate Judge Scanlon's decision is "wrong." *Barratt*, 2002 WL 335014, at *1. With respect to motive, Plaintiff also raises a new argument for the first time, which does not warrant *de novo* review. *See Kennedy*, 2006 WL 3704784, at *1 ("a district [court] judge will [] ordinarily refuse to consider arguments, case law and/or evidentiary material which could have been, but [were] not, presented to the magistrate judge in the first instance.") With respect to recklessness, Plaintiff reiterates the same objection to the R&R's finding that Plaintiff's allegations comprise an interpretation of scientific data, which the Court has overruled.

A. Motive

In support of its objections regarding the R&R's scienter findings, Plaintiff first argues that "the [TAC] alleges Defendants [Roivant and Wong] . . . were motivated to artificially inflate the price of Immunovant shares and delay disclosing [the risk of elevated cholesterol levels] to investors . . . until after they received their lucrative earnout shares." (Ptf. Obj. at 23.) Plaintiff contends that Magistrate Judge Scanlon "inappropriately dismissed" this allegation "as simply 'a generalized motive for incentive compensation.'" (Ptf. Obj. at 23) (quoting R&R at 35.)

This argument ignores the R&R's explanation that not only does the Third Amended Complaint allege "a generalized motive for incentive compensation," with respect to the allegation that "Mr. Wong and Roivant benefited from Immunovant's artificially inflated stock price by receiving earnout shares" (R&R at 35), the Third Amended Complaint also fails to plead that Defendants Roivant and Wong "[sold] such shares during the Putative Class Period" or that they received any actual benefit. (R&R at 34.) As noted by Defendants, "mere ownership in the absence of profit-taking does not establish a motive that would support a strong inference" of scienter. *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 367 (S.D.N.Y. 2003). Accordingly, Plaintiff's objection to the finding in the R&R that Plaintiff failed to allege adequate facts showing motive is overruled.

B. Recklessness

Plaintiff's arguments regarding scienter depend on the same interpretation of the scientific data addressed previously. Plaintiff alleges that "each of the Exchange Act Defendants had access to . . . (i) the results of the [] animal studies revealing substantial elevations in cholesterol; (ii) the medical studies and literature indicating albumin reductions and [] elevate[d] cholesterol levels; (iii) information . . . that early clinical trials failed to monitor cholesterol; and (iv) information concerning the testing procedures of other companies developing

[similar] compounds." (Ptf. Obj. at 24.) Plaintiff alleges that in light of Defendants' access to this information, Defendants should have known cholesterol elevations were an important potential risk. (*Id.*) As noted previously however, even accepting as true the allegation that Defendants had access to this information, Plaintiff's allegations regarding the "important potential risk" that should have been extrapolated from this data are rooted in Plaintiff's "interpretation of scientific data." (R&R at 40-41.) The Second Circuit has made clear that a plaintiff's interpretation of the scientific data is "not a basis upon which scienter can be sufficiently pled." (R&R at 40-41) (citing *Philip Morris*, 89 F.4th at 420). Because the Court has overruled Plaintiff's objections regarding whether this information constitutes an "interpretation of scientific data," the Court also overrules Plaintiff's objection to the R&R's finding that the interpretation of the data cannot form the basis for an allegation of recklessness.

C. Statements by Defendants Salzmann and Wong

Plaintiff also points to statements by Defendant Salzmann and Defendant Wong as evidence of scienter. First, Plaintiff notes that Defendant Salzman asserted, at one point, that "it's pretty hard to find any published literature or expert opinion on what the sequelae . . . of a mild albumin reduction would be." (Ptf. Obj. at 25.) Plaintiff argues that "whether

literature on a particular topic exists is a fact and not a disagreement." (Id.) Defendant Salzmann did not assert, in the quoted statement, that "literature on [the relevant] topic" does not "exist," only that "it's pretty hard to find" published literature. (*Id.*) That literature on a topic is "hard to find" is, of course, a statement of opinion.

Plaintiff also points to a statement by Defendant Wong that "people in the literature are generally asymptotic," which Plaintiff argues is "minimizing the impact of albumin reduction . . . by pointing to a lack of symptoms . . . even though those were two separate things." (*Id.*) The Court, on *de novo* review, agrees with the R&R's conclusion that "[a]t most, [] this allegation evidences disagreement as to the conclusions to be drawn from scientific studies." (R&R at 40 n.14.) As noted in the R&R and as instructed by the Second Circuit in *Philip Morris*, "a statement is 'misleading and actionable' only 'when the omitted contrary facts *substantially undermine* the conclusion that a *reasonable investor* would reach from the statement.'" (R&R at 21) (citing *Philip Morris*, 89 F.4th at 423 (emphasis in original)). Plaintiff does not allege adequate facts to support the conclusion that either Defendant Salzmann's or Defendant Wong's respective statements rise to the level of a material misstatement or omission or that either statement can form a

basis for any argument of individual scienter. Accordingly, this objection is overruled.

V. Control Person Liability

Finally, Plaintiff objects to the recommendation in the R&R that the Court dismiss Count III, which alleges violations of Section 15 of the Securities Act, and Count V, which alleges violations of Section 20(a) of the Exchange Act. As Plaintiff acknowledges, both Count III and Count V depend on the existence of a "primary violation" underlying any "control person liability." (Ptf. Obj. at 21, 26.) Plaintiff does not appear to object to the dismissal of these claims in the event that no primary violation is found. Nor could Plaintiff make such an objection because it would be contrary to the plain text of the statutes. Instead, Plaintiff argues that "[s]ince Plaintiff adequately alleges the underlying . . . claims, Plaintiff objects to the R&R's recommendation that" the Section 15 and Section 20(a) claim "be dismissed. (Ptf. Obj. at 21, 26.) As set forth previously, each of Plaintiff's objections with respect to the claims alleging primary violations of the Securities Act and Exchange Act are respectfully overruled. Accordingly, Plaintiff's objection to the dismissal of Counts III and V must be overruled as well.

CONCLUSION

For the foregoing reasons, on *de novo* and clear error review, the Court respectfully overrules Plaintiff's objections and adopts and affirms the well-reasoned and thorough R&R issued by Magistrate Judge Scanlon in its entirety. Defendants' motions to dismiss the Third Amended Complaint are **GRANTED**. The Third Amended Complaint is **DISMISSED** in its entirety with prejudice.

Federal Rule of Civil Procedure 15(a) counsels that leave to amend a complaint shall be freely given "when justice so requires." Although the Second Circuit has advised that "the usual practice upon granting a motion to dismiss [is] to allow leave to replead," *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991), Plaintiff has already been granted leave to amend its Complaint three times. *See Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008) ("leave to amend, though liberally granted, may properly be denied for . . . failure to cure deficiencies by amendments previously allowed") (internal citations omitted). Moreover, Plaintiff "can plead no facts that would overcome the [] deficiencies discussed above." *Johnson v. Maximus Services LLC*, No. 22-cv-2935 (AMD), 2023 WL 5612826, at *6 (E.D.N.Y. Aug. 30, 2023). As such, the Court will not grant further leave to amend.

The Clerk of Court is respectfully requested to enter Judgment in favor of Defendants and to close this case.

SO ORDERED.

Dated: March 29, 2024
Brooklyn, New York

KIYO A. MATSUMOTO
United States District Judge
Eastern District of New York